K072952

Attachment B:

NOV 16 2007

Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Medical Systems, Ultrasound and Primary Care Diagnostics
PO Box 414
Milwaukee, WI 53201

Contact Person: Allen Schuh,
Manager, Ultrasound Regulatory Affairs
Telephone: 414-721-3992; Fax: 414-721-3899

Date Prepared: October 17, 2007

2. Device Name: GE EchoPAC™ Ultrasound Image Workstation
System, Image Processing, Radiological , 21 CFR 892.2050, 90-LLZ

3. Marketed Device: GE Vivid 7 Diagnostic Ultrasound with EchoPAC - K060542
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

4. Device Description: The GE EchoPAC is an Ultrasound Image Analysis and Review Workstation optimized for ultrasound images that are acquired primarily via the GE Vivid family of diagnostic ultrasound systems. It is sold either with computer hardware or as software only with hardware specifications.

5. Indications for Use: For diagnostic review and analysis of ultrasound images acquired under various modes of operation including B, M, Color M modes, Color, Power, Pulsed & CW Doppler modes, Coded Pulse, Harmonic and Realtime 3D. Specific clinical applications include: Fetal; Abdominal; Urology (including prostate); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional; Transesophageal (TEE); Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular)

6. Comparison with Predicate Device: The GE EchoPAC™ is the same device previously cleared as an accessory to the Vivid 7 ultrasound system under K060542. It has the technological characteristics, key safety and effectiveness features, physical design, construction, and materials, and has essentially the same intended uses and post acquisition characteristics as the Vivid 7 ultrasound system.

Section b):

1. Non-clinical Tests: The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. It is further verified for system compatibility with the devices with which it communicates. Computer hardware is certified to applicable safety standards.

2. Clinical Tests: None required to confirm safety and effectiveness. However, evaluation in a clinical setting is performed to help assure reliability and compatibility within the intended network environment.

3. Conclusion: Intended uses and other key features of the device are consistent with traditional clinical practice, FDA guidelines and established methods of handling patient examination images and data. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485:2000 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through internal and independent quality system audit. PACS devices and medical information management systems in general have accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE EchoPAC™ is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

Mr. Allen Schuh
Manager, Ultrasound Regulatory Affairs
General Electric Company
GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
9900 Innovation Drive
WAUWATOSA WI 53226

Re: K072952
Trade/Device Name: GE EchoPAC™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 17, 2007
Received: October 18, 2007

Dear Mr. Schuh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment E

Indications for Use

510(k) Number (if known): K072952

Device Name: GE EchoPAC™

Indications For Use: The GE EchoPAC workstation is indicated for diagnostic review and analysis of ultrasound images acquired under various modes of operation including B, M, Color M modes, Color, Power, Pulsed & CW Doppler modes, Code Pulse, Harmonic and Realtime 3D. Specific clinical applications include: Fetal; Abdominal; Urology (including prostate); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional; Transesophageal (TEE); Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

~~Over-The-Counter Use~~ _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072952